

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the claims

1. (previously presented) A drug formulation comprising
danazol in an amount providing regionally effective, not systemically effective, levels of
danazol when administered transdermally to the breast, to provide relief from benign diseases or
disorders of the breast,

wherein the danazol is formulated in a hydroalcoholic gel comprising N-methyl-2-
pyrrolidone or 2-pyrrolidone in an effective amount to solubilize danazol and to deliver danazol
across the stratum corneum to the underlying breast tissue.

2.-9. (cancelled)

10. (withdrawn, previously presented) A method for treating a disease or disorder of the
breast treatable with danazol comprising

topically administering to the breast of a patient,

a drug formulation comprising an effective amount of danazol in an amount providing
regionally effective, not systemically effective, levels of danazol when administered
transdermally to the breast tissue, to provide relief from benign diseases or disorders of the
breast,

wherein the danazol is formulated in a hydroalcoholic gel comprising N-methyl-2-
pyrrolidone or 2-pyrrolidone in an effective amount to solubilize danazol and to deliver danazol
across the stratum corneum to the underlying breast tissue.

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11-16. (cancelled)

17. (withdrawn, currently amended) The method of claim 10 wherein the benign disease of the breast is selected from the group consisting of mastalgia, mastodynia, and fibrocystic breast disease[.,].

18. (cancelled)

19. (withdrawn, previously presented) The method of claim 10 wherein the region is the breast, areola, and underlying musculature of the chest.